

Allowable Subject Matter

Applicants thank the Examiner for noting that claim 61 is directed to allowable subject matter.

Withdrawal of Non-Elected Subject Matter

Claims 63-65 stand withdrawn from consideration as allegedly directed to an invention that is patentably distinct from the invention originally claimed. More specifically, the Action alleges that each claim is drawn to polynucleotides falling within a different discrete range of lengths, and, therefore, each claim requires non-coextensive sequence and literature searches. Thus, the Action requests that claims 63-65 are cancelled.

Applicants respectfully disagree with the Examiner's statement that the claims require an upper limit on the size range of the claimed polynucleotides. Nonetheless, Applicants have cancelled claims 63-65, as requested, without acquiescence to this basis of rejection. However, to ensure that the application contains claims directed to fragments of the polynucleotide of SEQ ID NO:808, thus preserving the scope of the originally filed claims, Applicants have submitted new claim 69 for consideration. Claim 69 is directed to isolated polynucleotides comprising at least 175 contiguous residues of SEQ ID NO:808, wherein the polynucleotide can be used in the detection of lung cancer. Applicants respectfully submit that the subject matter of this claim is encompassed by original claim 4 and, therefore, does not constitute new matter. Support for claim 69 is provided in the application as originally filed, *e.g.*, at page 67, lines 6 to 12. Applicants further submit that the search performed for the subject matter of original claim 4 would have uncovered all relevant art related to the subject matter of claim 69, so a new search is not required. Applicants respectfully request that claim 69 be entered and considered at this time.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 62 and 66 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly define the scope of the subject matter. More specifically, the Action alleges that the claims are drawn to products useful in the diagnosis of any cancer, while the specification discusses only lung cancer.

Without acquiescence to this basis of rejection, Applicants have amended claims 62 and 66 to refer to "lung cancer," instead of "cancer." Applicants submit that support for this amendment is provided throughout the specification as originally filed, including, *e.g.*, Example 1, which describes the finding that L552S is overexpressed in lung tumor tissue as compared to normal lung tissue. Applicants respectfully request that this basis of rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 62, 66, 67, and 68 stand rejected under 35 U.S.C. § 112, first paragraph, on the alleged basis that the specification does not reasonably provide enablement for the use of polynucleotides having at least 90% identity with SEQ ID NO:808 for the diagnosis of any type of cancer other than lung cancer.

Without acquiescence to this basis of rejection and solely to expedite prosecution, Applicants have amended claims 62, 66, 67, and 68 to recite "lung cancer," rather than "cancer," as described above. Applicants submit that the specification is clearly enabling regarding the use of the claimed polynucleotides for the diagnosis of lung cancer, as recognized by the Action on page 4, lines 2-3. Accordingly, Applicants respectfully request that this basis of rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 62 and 66-68 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter lacking adequate written description in the specification. More specifically, the Action alleges that the genus of nucleotide sequences having at least 90% identity to SEQ ID NO:808 lacks sufficient written description, since the genus is highly variable, and the effects of changes in structure are largely unpredictable. Furthermore, the Action alleges that the specification does not indicate the common attribute of the claimed polynucleotides that is required for their usefulness in the detection of lung cancer.

Applicants respectfully traverse this basis of rejection and submit that the claims are adequately described in the instant application. Contrary to the Action's position, Applicants submit that the skilled artisan would readily understand that the claimed genus of polynucleotides with at least 90% identity to SEQ ID NO:808 were in the possession of Applicants at the time of

filing the instant application. Applicants submit that the skilled artisan would immediately recognize that diagnostic uses, for example, of the claimed polynucleotides require merely their ability to hybridize to polynucleotides of SEQ ID NO:808. Applicants further submit that the skilled artisan would also recognize that sequences with at least 90% identity to SEQ ID NO:808 would, indeed, hybridize to polynucleotides of SEQ ID NO:808 and that the only necessary common attribute of the claimed polynucleotides is their sequence identity to SEQ ID NO:808. Applicants thus submit that to accept the Action's position that Applicants were only in possession of polynucleotides consisting of the single species of SEQ ID NO:808 would inappropriately exclude an entire class of polynucleotides related to SEQ ID NO:808 that the skilled individual would appreciate were in Applicants' possession at the time of filing. This understanding and expectation on the part of the skilled artisan is submitted to be soundly based upon fundamental scientific principles.

In addition, Applicants submit that under the Examination Guidelines set forth by the Patent and Trademark Office, the written description requirement for a claimed genus may be satisfied by the description of a representative number of species or the disclosure of relevant, identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶1, "Written Description" Requirement, 66 Fed. Reg. 1099, at 1106. Applicants submit that the instant application meets both criteria. Applicants submit that the instant specification describes a representative number of claimed species by providing the sequence of SEQ ID NO:808, as well as describing sequences with at least 90% identity to these polypeptides. Applicants also note that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species the genus embraces. *Id.* Applicants further submit that by providing a reference sequence and the percent identity limitation, the specification adequately describes a representative number of claimed variants, since one skilled in the art would readily identify a claimed sequence and recognize that Applicants were in possession of said sequence at the time the application was filed. In addition, Applicants submit that the instant specification discloses sufficient identifying characteristics for L552S-related polynucleotides with at least 90% identity to the polynucleotide of SEQ ID NO:808, since it provides both a reference sequence and percent identity limitations.

Polynucleotides of this genus clearly share the structural characteristic of at least 90% identity with the polynucleotide sequence of SEQ ID NO:808. In light of these comments, Applicants respectfully request that this basis of rejection be withdrawn.


Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"

Applicants respectfully submit that all claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Applicants' attorney wishes to express her willingness to engage in a telephone interview to further the status of this application if any further concerns need to be addressed.

Respectfully submitted,

Tongtong Wang et al.

Seed Intellectual Property Law Group PLLC



Carol D. Laherty, Ph.D.
Registration No. 51,909

CDL:sd

Enclosure:

Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031



VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-3, 11-60, and 63-65 have been cancelled.

Claims 62, 66, and 67 have been amended as follows:

62. (Amended) An isolated polynucleotide comprising a sequence having at least 90% identity with the entirety of the sequence of SEQ ID NO:808, wherein the polynucleotide can be used in the detection of lung cancer.

66. (Amended) An isolated polynucleotide comprising the complement of a polynucleotide of any one of claims 61-~~65~~62 or 69, wherein the polynucleotide can be used in the detection of lung cancer.

67. (Amended) An expression vector comprising a polynucleotide according to any one of claims 61-~~66~~62 or 69.

D:\NrPortbl\iManage\SANDID\313729_1.DOC